CG Oncology to Present Results on Cretostimogene Grenadenorepvec at the Society of Urologic Oncology (SUO) 25th Annual Meeting

Nov 20, 2024

Includes Late-Breaking Abstract on Results of Phase 3 BOND-003 Trial of Cretostimogene Monotherapy in High-Risk BCG-Unresponsive NMIBC and Four Trials in Progress Posters

IRVINE, Calif., Nov. 20, 2024 (GLOBE NEWSWIRE) -- CG Oncology, Inc. (NASDAQ: CGON), a late-stage clinical biopharmaceutical company focused on developing and commercializing a potential backbone bladder-sparing therapeutic for patients with bladder cancer, today announced that four Trials in Progress Posters highlighting cretostimogene, in addition to the recently announced late breaking abstract on BOND-003, will be presented at the Society of Urologic Oncology (SUO) 25th Annual Meeting taking place at the Sheraton Dallas Hotel in Dallas, TX, from December 4 - 6, 2024.

Details on the late-breaking abstract and posters are as follows:

Late-Breaking Abstract:

Topline Results from BOND-003: A Phase-3 Study of Intravesical Cretostimogene Grenadenorepvec for the Treatment of High-Risk BCG-Unresponsive NMIBC with CIS
Podium Presentation
Presenter: Mark D. Tyson, M.D., Urologic Oncologist at Mayo Clinic, Scottsdale, AZ
Presentation Date & Time: December 5, 2024 at 11:45 AM Central Daylight Time
Location: The Sheraton Dallas Hotel, Dallas, TX

Trial in Progress Posters:

BOND-003- Cohort P: A Multi-national, Single-arm Study of Intravesical Cretostimogene Grenadenorepvec for the Treatment of High-Risk, Papillary Only, BCG-Unresponsive Non-Muscle Invasive Bladder Cancer
Poster Number: 125
Presenter: Mark D. Tyson, M.D., Urologic Oncologist at Mayo Clinic, Scottsdale, AZ
Presentation Date & Time: December 5, 2024 from 2:15-3:15 PM Central Daylight Time
Location: The Sheraton Dallas Hotel, Dallas, TX

PIVOT-006: A Phase 3, Randomized Study of Adjuvant Intravesical Cretostimogene Grenadenorepvec versus Surveillance for the Treatment of Intermediate-Risk Non-Muscle Invasive Bladder Cancer
Poster Number: 126
Presenter: Robert S. Svatek, M.D., Urologic Oncologist at University of Texas Health Science Center, San Antonio, TX
Presentation Date & Time: December 5, 2024 from 2:15-3:15 PM Central Daylight Time
Location: The Sheraton Dallas Hotel, Dallas, TX

CORE-008: A Phase 2, Multi-Arm, Multi-Cohort, Open-Label Study to Evaluate the Safety and Efficacy of Cretostimogene Grenadenorepvec in Participants with High-Risk Non-Muscle Invasive Bladder Cancer
Poster Number: 235
Presenter: Trinity J. Bivalacqua, M.D., Ph.D., Urologic Oncologist at University of Pennsylvania, Philadelphia, PA
Presentation Date & Time: December 6, 2024 from 1:45-2:45 PM Central Daylight Time
Location: The Sheraton Dallas Hotel, Dallas, TX

The Cretostimogene Grenadenorepvec Expanded Access Program in Patients with Non-Muscle Invasive Bladder Cancer Unresponsive to Bacillus Calmette-Guerin
Poster Number: 236
Presenter: Sarah P. Psutka, M.D. M.Sc., Urologic Oncologist at University of Washington, Seattle, WA
Presentation Date & Time: December 6, 2024 from 1:45-2:45 PM Central Daylight Time
Location: The Sheraton Dallas Hotel, Dallas, TX

About Cretostimogene Grenadenorepvec
Cretostimogene is an investigational, intravesically delivered oncolytic immunotherapy being evaluated in BOND-003, a Phase 3 clinical trial for the treatment of patients with high-risk Non-Muscle Invasive Bladder Cancer (NMIBC) who are unresponsive to Bacillus Calmette Guerin (BCG) therapy. Cretostimogene is also being evaluated in a Phase 3 monotherapy clinical trial (PIVOT-006) in patients with intermediate-risk NMIBC. In addition, cretostimogene is being evaluated in an investigator-sponsored clinical trial in combination with nivolumab for the treatment of muscle invasive bladder cancer. Cretostimogene is an investigational, intravesically delivered oncolytic immunotherapy candidate, and its safety and efficacy have not been established by the FDA or any other health authority.

About CG Oncology
CG Oncology is a late-stage clinical biopharmaceutical company focused on developing and commercializing a potential backbone bladder-sparing therapeutic for patients afflicted with bladder cancer. CG Oncology sees a world where urologic cancer patients may benefit from our innovative immunotherapies to live with dignity and have an enhanced quality of life. To learn more, please visit: www.cgoncology.com.

Forward Looking Statements
CG Oncology cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. The forward-looking statements are based on our current beliefs and expectations and include, but are not limited to, the potential therapeutic benefits of cretostimogene in combination with nivolumab in Muscle Invasive Bladder Cancer, the potential therapeutic benefits of

cretostimogene for high-risk and intermediate-risk NMIBC patients; and the anticipated timing of BOND-003 topline data. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in our business, including, without limitation: additional patient data related to cretostimogene in combination with nivolumab that continues to become available may be inconsistent with the data produced as of the data cutoff, and further analysis of existing data and analysis of new data may lead to conclusions different from those established as of the date hereof; results from earlier clinical trials and preclinical studies not necessarily being predictive of future results; unexpected adverse side effects or inadequate efficacy of cretostimogene that may limit its development, regulatory approval, and/or commercialization; potential delays in the commencement, enrollment and completion of clinical trials; and other risks described in our filings with the Securities and Exchange Commission (SEC), including under the heading “Risk Factors” in our annual report on Form 10-K and other filings that we make with the SEC from time to time (which are available at http://www.sec.gov). You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

Contacts:

Media
Sarah Connors
Vice President, Communications and Patient Advocacy, CG Oncology
(508) 654-2277
sarah.connors@cgoncology.com

Investor Relations
Chau Cheng
Vice President, Investor Relations, CG Oncology
(949) 342-8939
chau.cheng@cgoncology.com